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GROUP 3200

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

Bruce G. KANIA et al.

SERIAL NO: 08/611,306

FILED: March 5, 1996

FOR: GEL AND CUSHIONING DEVICES



: EXAMINER: Willse

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: GROUP ART UNIT: 3308

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DECLARATION UNDER 37 CFR 1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I, Bruce Kania, declare as follows:

The tube sock covering of the above-identified application differs from the Silosheath® sock in the following respects, and provides several benefits, as follows:

1. With gel only on the inside, and fabric on the outside, the covering (liner) slides into a socket, even when the socket is tightly form fitting, as in new socket, and even when an amputee's residuum (stump) swells, which can happen coincident with various activity or lack of activity. This also means you don't get anywhere near the amount or variety of noise effects from our product as from a product like Silosheath® with gel or rubber on the outside.

2. The Luxury Liner® (i.e., the tube sock covering of the invention) offers a unique level of stability, sometimes described as "integrity" or "solidness", or "dependability". This results from the design which allows for circumferential elasticity, but minimal axial stretch, so that even when unusual circumstances stress the limit, this new and surprising stability feature makes this design particularly important at critical moments to the amputee user.

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3. The Luxury Liner® integrates total socket interface all in one product. This results in a new and surprising level of comfort and biofidelic response, i.e., a natural, lifelike limb performance relative to sense of "where the leg is now". Other products like Silosheath® require additional layers of material, like wool socks, and pelite liners, all of which impinge or reduce this biofidelic sense of enhanced proprioception.

4. Some amputees have noticed significant reductions in perspiration associated with Alpha® and Luxury Liners®. We surmise this is due in part to the same feature described above, wherein the combination of circumferential tension and minimal axial stretch result in a comfortable wear experience while actually generating a level of back pressure which results in reduced perspiration between liner and residuum.

5. Another feature that has generated surprising results is related to both thickness and softness of our product. While standard thinking in the prosthetics industry is that less weight and less insulative effect is best, we have found that our gel characteristics are optimized by a higher level of thickness, and that the result is the enhanced proprioceptive experience so often described in product testimonials. Essentially, our product's thicker versions are dramatically more popular than our thinnest model. Despite the other negatives associated with thickness, i.e., added bulk and its affect on cosmesis, added weight, added insulative effect, added expense, we have been surprised to find that increased thickness and gel generates comfort and performance that significantly outweigh the negatives. We could have produced a thinner, lighter product that was also relatively durable, yet due to the unexpected but dramatic benefits associated with the thickness/softness effect, even our thinnest, lightest model is significantly bulkier than a product like the Silosheath®.

6. Another unique feature of our invention relates to ease of use. As an example, I recently learned to scuba dive. Since I did not have a prosthetic leg designed for swimming I would simply walk to the edge of the pool, pull my suspension sleeve down, leaving my prosthesis at pool side, and without removing my liner, i.e., the invention tube sock covering, entered the water and swam. Circumferential tension kept the liner in place, protecting the relatively sensitive residuum. Upon climbing out of the pool I simply stepped into the socket, pulled the suspension sleeve up, and walked away. Had I been wearing wool socks and pelite liner, or Silosheath® and wool socks and/or pelite liner, all would have had to have been removed and kept dry in this situation. The Silosheath® probably would have floated or washed off immediately had I attempted to wear such a device in the water. There are numerous other examples of how, in the normal course of life, convenience associated with this invention serves to improve life for amputees. Although such improvements may seem relatively minor, let me assure you that as an amputee, such improvements are welcome.

7. Another surprise connected with this invention has been that the circumferential tension associated with several features—thickness, gel, elastic tension of the fabric, etc. has resulted in a surprising enhanced vascularization effect. What this means is that where in the past an amputee may have had to make several adjustments relative to volume in the prosthesis socket over the course of a day, as in adding or reducing socks or liners, our invention somehow tends to equalize vascularization, minimizing the discomfort that would otherwise motivate socket adjustment.

8. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under
Section 1001 of Title 18 of the United States Code and that such willful false statements may
jeopardize the validity of this application or any patent issuing thereon.

9. Further deponent saith not.

Bruce Kania
Signature

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Date

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